| | NADA Number: 008-763 | | | | | |
|-----------------------------|--|--|--|--|--|--|
| Trade Name | Terramycin® Ophthalmic Ointment with Polymyxin | | | | | |
| Sponsor | Pfizer, Inc. | | | | | |
| Ingredients | Oxytetracycline Hydrochloride Polymyxin B Sulfate | | | | | |
| Species | Cat, no use class stated or implied Horse, no use class stated or implied Dog, no use class stated or implied Cattle, no use class stated or implied Sheep, no use class stated or implied | | | | | |
| Routes of Administration | Opthalmological | | | | | |
| Dose Form | Ointment | | | | | |
| Drug Form | Ointment | | | | | |
| Dispensing Status | OTC | | | | | |
| | 524.1662b Oxytetracycline hydrochloride, polymyxin B sulfate ophthalmic ointment. | | | | | |
| | Specifications: Each gram of the ointment contains oxytetracycline hydrochloride equivalent to 5 milligrams of oxytetracycline and 10,000 units of polymyxin B sulfate. | | | | | |
| | Conditions of use: | | | | | |
| | Dogs | | | | | |
| | Amount: It is administered topically to the eye two to four times daily. | | | | | |
| | Indications: The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae E. coli, and A. aerogenes (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in dogs); ocular infections due to secondary bacterial complications associated with distemper in dogs; and ocular infections due to bacterial inflammatory conditions which may occur secondary to other diseases in dogs. | | | | | |
| | Limitations: Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken. | | | | | |
| | Cats | | | | | |
| | Amount: It is administered topically to the eye two to four times daily. | | | | | |

Indications: The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae E. coli, and A. aerogenes (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in cats) and ocular infections due to bacterial inflammatory conditions which may occur secondary to other diseases in cats.

Limitations: Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

Cattle

Dosage Amount, Indications & Limitations Amount: It is administered topically to the eye two to four times daily.

Indications: The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae E. coli, and A. aerogenes (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in cattle) and ocular infections due to bacterial inflammatory conditions which may occur secondary to other diseases in cattle.

Limitations: Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

Sheep

Amount: It is administered topically to the eye two to four times daily.

Indications: The drug is used for the prophylaxis and local treatment of superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae E. coli, and A. aerogenes (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in sheep) and ocular infections due to bacterial inflammatory conditions which may occur secondary to other diseases in sheep.

Limitations: Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken.

Horses

Amount: It is administered topically to the eye two to four times daily.

Indications: The drug is used for the prophylaxis and local treatment of

| | superficial ocular infections due to oxytetracycline- and polymyxin-sensitive organisms. These infections include the following: Ocular infections due to streptococci, rickettsiae E. coli, and A. aerogenes (such as conjunctivitis, keratitis, pinkeye, corneal ulcer, and blepharitis in horses) and ocular infections due to bacterial inflammatory conditions which may occur secondary to other diseases in horses. Limitations: Allergic reactions may occasionally occur. Treatment should be discontinued if reactions are severe. If new infections due to nonsensitive bacteria or fungi appear during therapy, appropriate measures should be taken. |
|------------|--|
| Tolerances | Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, finfish and lobster. Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows: a. 2 parts per million (ppm) in muscle b. 6 ppm in liver c. 12 ppm in fat and kidney d. 0.3 ppm in milk. |